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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,435	08/23/2006	Paul Fraser	090931-380575	1436

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EXAMINER	
BALLARD, KIMBERLY	
ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,435	FRASER, PAUL	
	Examiner	Art Unit	
	Kimberly Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-11,13-16,32-35,40-50 and 57-63* is/are pending in the application.

4a) Of the above claim(s) *32-35,40-50 and 57-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-11,13-16,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

1. Claims 1, 3, and 50 have been amended and new claims 62 and 63 have been added the amendment filed March 15, 2010. Following the amendment, claims 1-3, 9-11, 13-16, 32-35, 40-50 and 57-63 are pending in the present application.

2. Claims 32-35, 40-50, and 57-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 31, 2009.

4. Claims **1-3, 9-11, 13-16, 62** and **63** are under examination in the current office action.

Maintained and New Rejections, Necessitated by Amendment

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 9-11, 13-16 and 62-63, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0119926 A1 to Fraser (published August 29, 2002). This rejection is maintained for reasons of record and is further applied to new claims 62-63 as detailed below.

Claim 1, as amended, recites an antifibrillogenic agent for inhibiting amyloidosis and/or for cytoprotection comprising a peptide consisting of ANX (SEQ ID NO: 28), wherein X is any amino acid except cysteine, or an isomer thereof, a retro or a retro-inverso isomer thereof, or a salt thereof. Dependent claims recite that X is isoleucine (I) or phenylalanine (F) (claims 2-3), that the peptide is ANX (SEQ ID NO: 28) with X being any amino acid expect cysteine (claim 9), the peptide is ANX with X being I or F (claim 10), or the peptide is ANF (SEQ ID NO: 24) (claim 11), the amyloidosis is IAPP-related (claim 13), or the amyloidosis is type I or type 2 diabetes (claim 14). Claims 15, 16, 62 and 63 recite a composition for inhibiting amyloidosis and/or for cytoprotection, comprising a therapeutically effect amount of the antifibrillogenic agent of claim 1, 9, 10, or 11 respectively, in association with a pharmaceutically-acceptable carrier.

Fraser teaches antifibrillogenic agents, and compositions thereof, for inhibiting amyloidosis and/or for cytoprotection (see abstract and paragraph [0075]). The agents are taught to include peptides or isomers, retro or retro-inverso isomers, or salts thereof (see [0068]). Fraser teaches that the antifibrillogenic agents of the invention may be used for the treatment of type I or type II diabetes (see [0030]) and other amyloidoses (see [0066]), such as to control IAPP aggregation in IAPP-related amyloidosis (see

[0074] and claim 13 on p. 16). Additionally, Fraser teaches compositions comprising a therapeutically effective amount of the antifibrillogenic agents in association with a pharmaceutically acceptable carrier (see [0078]), which addresses recited limitations of claims 15, 16, 62 and 63.

Fraser discloses the peptides LANFLV (SEQ ID NO: 6) and ANFLVH (SEQ ID NO: 7), both of which are taught as antifibrillogenic agents that *comprise* a peptide *consisting of* ANF, which is the instantly recited SEQ ID NO: 24, or the instant SEQ ID NO: 28 (ANX) wherein X is F. These peptides are evidenced to be capable of inhibiting beta-sheet formation of IAPP (see, for example, [0099] and [0181-0182]).

Response to Arguments

7. In the response filed March 15, 2010, Applicant states that the claims have been amended to replace "consisting essentially of" with "consisting", and thus no longer read upon the prior art. With respect to claims 9-11 and paragraph [0097], Applicant argues that the paragraph is a general statement, and that tripeptides were not disclosed in the prior art. Applicant asserts that there were no suggestions as to how the hexapeptides could be truncated or substituted or which tripeptides or fragments would show the desired or enhanced activity, and that paragraph [0130] evidences that even slight changes can have an effect on activity.

8. Applicant's arguments have been fully considered but they are not persuasive. The instantly recited claims, even as amended, are still interpreted as reading upon the prior art reference because the claims recite an antifibrillogenic agent *comprising* a peptide *consisting of* ANX (or ANF). In other words, the LANFLV or ANFLVH

antifibrillogenic agents taught by Fraser each comprise the tripeptide consisting of ANF. Therefore, regardless of the teachings of paragraph [0097], claims 9-11 would still be anticipated because the claims further define the peptide comprised by the antifibrillogenic agent. Accordingly, the rejection of claims 1-3, 9-11, 13-16 and 62-63 is maintained.

9. Claims 1 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,426,324 to Meienhofer (issued January 17, 1984).

Meienhofer teaches the tripeptide Ala-Glu-Asn (AEN) (see column 2, lines 1-2, and Example 1 at column 4). Meienhofer also teaches formulation of the compounds of the invention, which include the aforementioned tripeptide AEN, into a pharmaceutical composition for administration to mammals, wherein the peptide is reconstituted prior to use in water or saline (see column 4, lines 32-43), which meets the limitations of a pharmaceutically-acceptable carrier in present claim 15.

Instant claim 1 recites that the antifibrillogenic agent comprises a peptide consisting of ANX, wherein X is any amino acid except cysteine, or an isomer thereof. Meienhofer's tripeptide AEN is an isomer of ANX, wherein X is E. Thus, as the peptide AEN meets the structural limitations of the claim, it would be expected to inherently possess antifibrillogenic and/or cytoprotective activities as claimed. A chemical composition and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)), as are their processes and yields (*In re Von Schickh*, 362 F.2d 821, 150 USPQ 300 (CCPA 1966)). Therefore, if the prior art teaches the identical chemical structure,

the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

And regarding claims 13 and 14, the recitation of "for inhibiting amyloidosis" does not confer patentable weight because it appears solely in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See also MPEP § 2111.02, section II. Accordingly, the Meienhofer reference anticipates the present invention recited in claims 1 and 13-15.

10. Claims 1 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7,056,889 to Villanueva et al. (issued June 6, 2006, filed December 16, 2002.

Villanueva et al. teach the peptide Gly-Ala-Asn (GAN, SEQ ID NO: 18) (see Table 1 at column 7), and pharmaceutical compositions comprising said peptide (see Abstract and paragraph spanning columns 16-17). GAN is a peptide isomer of ANX (i.e., XAN), wherein X is glycine (G). Thus, as the peptide GAN meets the structural limitations of claim 1, GAN would be expected to inherently possess antifibrillogenic and/or cytoprotective activities as claimed. A chemical composition and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)), as are their

processes and yields (*In re Von Schickh*, 362 F.2d 821, 150 USPQ 300 (CCPA 1966)). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

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Claim Objections

11. Claim 62 is objected to because of the following informalities: in line 2 of the claim, the word "or" is misspelled as "ro". Appropriate correction is required.

Conclusion

12. No claims are allowed.

13. This application contains claims 32-35, 40-50 and 57-61 drawn to an invention nonelected with traverse in the reply filed on July 31, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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